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Study Title

BASF's New Engenia Application and Factors Identified in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020) ("*NFFC*")

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Fulfills EPA Guideline

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GOOD LABORATORY PRACTICES STATEMENT

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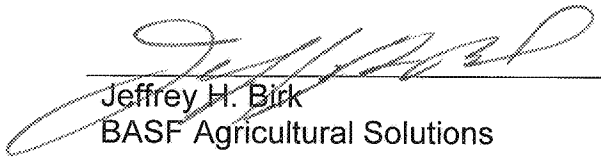

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INTRODUCTION

BASF is submitting information and positions of BASF Corporation ("BASF") in support of BASF's new application to register an Engenia product (7969-UTE). The data and information contained within this submission has been previously provided to EPA via email as a courtesy copy to facilitate the registration decision process for Engenia herbicide.

October 8, 2020

Document Processing Desk (REG)
Ms. Emily Schmid
Product Management (25)
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Office of Pesticide Programs
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

Subject: BASF's New Engenia Application and Factors Identified in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020) ("*NFFC*")

Dear Ms. Schmid:

I write to convey information and positions of BASF Corporation ("BASF") in support of BASF's new application to register an Engenia product. In *NFFC*, a panel of the Ninth Circuit vacated EPA's 2018 registration of a prior version of Engenia (and other products) for over-the-top ("OTT") use. As you know, the Court's ruling was based on portions of the administrative record (determined by the parties to the litigation, which did not include BASF) that was before EPA at the time of its 2018 registration decisions. Based on that partial record, and the specific product use instructions and limits adopted by EPA in 2018, the Court concluded that EPA's 2018 decision document failed to acknowledge three potential risks, and failed to adequately weigh three other potential risks – each relating to potential off-site product movement and claimed harm to non-target plants.

EPA now possesses extensive Engenia studies and information that were not before the Court. Further, BASF's application to register a new Engenia product proposes substantial use limits and other changes that further address any risk of off-site movement or harm. These additional data and restrictions will allow EPA to fully address and resolve the concerns identified by the Ninth Circuit. This letter highlights some of the ways that the current data, and BASF's proposed new Engenia product and use parameters, address the six issues identified by the Ninth Circuit in *NFFC*.

Total number of U.S. acres planted with dicamba-tolerant soy and cotton seed

In *NFFC*, the Ninth Circuit opined that EPA had improperly cited prior-year information about the total number of areas planted with dicamba-tolerant ("DT") soy and cotton seed, when more up-to-date information for 2018 was or should have been available to EPA at the time of its decision. To the extent that the absolute number of acres planted is simply not relevant to EPA's registration decision, EPA should make that

clear. Either way, EPA should also ensure that it directly addresses the concern identified by the Court by referencing the best and most current acres planted data in the decision document.

While USDA compiles survey data estimating *total* U.S. soybean and cotton acres planted in 2020, to our knowledge USDA does not publish acres-planted figures for *DT* soybean or cotton. In addition to other information that might be available to EPA directly from USDA or from other sources, we are aware of meaningful estimates that have already been provided to EPA by knowledgeable parties. With respect to DT cotton, the National Cotton Council's letter to EPA dated September 10, 2020, states that 8.5 million acres of DT cotton were planted in 2020. CropLife America's letter to EPA dated September 17, 2020, states that approximately 64 million acres of both DT soy and cotton seeds combined were planted during the 2020 growing season. These figures are reasonably consistent with BASF's best estimates for 2020: approximately 9 million acres planted of DT cotton and 51 million acres planted of DT soybean. To the extent acres planted are relevant to EPA's registration decision, EPA should use the most reliable information available to it – and where figures vary EPA should use the most conservative figure in each instance.

Whether complaints received by state departments of agriculture under-reported or over-reported actual off-target impacts, and whether EPA could seek to quantify or estimate the amount of economic harm

Two of the six issues identified by the Ninth Circuit relate to reports of off-target impacts, and whether EPA could reliably estimate the amount of economic harm from off-site movement. Specifically, the Ninth Circuit concluded that the "record clearly shows that complaints understated the amount of dicamba damage." *NFFC* at 1137. The Court also concluded that EPA "refused to quantify or estimate the amount of damage caused by OTT application of dicamba herbicides, or even to admit that there was any damage at all." *Id.* at 1138.

BASF disagrees with the Court's assessment of the record that was before it. That aside, additional Engenia studies and information now possessed by EPA, and the substantial added restrictions on the use of the proposed new Engenia product that further reduce risks of off-site movement, confirm that EPA's approval of the requested new Engenia registration will pose no unreasonable risk to the environment, taking into account past reports of claimed off-target impacts.

The numbers of off-site incident reports continued to diminish after EPA's 2018 registration decision, and past incident reports did not translate to actual harm.

As EPA is aware, there are many reasons why grower reports alleging crop damage generally provide no reliable evidence of actual off-site movement of dicamba from OTT use on soybeans and cotton, nor of the existence or extent of any actual harm caused by such alleged off-site movement. Among other things, soybean plants are particularly sensitive to auxins, a category that includes several other pesticide active

ingredients beyond dicamba. The same visual plant symptoms (*e.g.*, leaf cupping) cited in some reports would be caused by exposures to any auxin product, not only OTT dicamba use on soybean or cotton.[1] Therefore, incident reports provide no reliable evidence of causation. The reports also do not indicate the number of acres implicated by the observed visual effects, the growth stage of the non-target crop, or the magnitude of the alleged exposure. Further, as detailed below, the data demonstrate that visual soybean plant effects such as leaf cupping often do not translate to any actual harm to the crop (*e.g.*, yield) and therefore these crop incident reports provide no reliable evidence of economic harm. Where incident reports have been followed up by investigation by state authorities or a registrant, no evidence has been publicized to establish widespread and economically-significant crop damage attributable to OTT dicamba use on soybeans and cotton.

Even putting that aside, total numbers of dicamba incident reports to states have fallen dramatically from 2016 to 2020. Nationwide, the total number of such reports fell by over 50% from 2017 to 2020. Per 100,000 acres of DT crops planted, complaints fell even more dramatically. In 2017, there were approximately 43 complaints per 100,000 DT acres. In each of 2018 and 2019, there were approximately 26 complaints per 100,000 DT acres. In 2020, complaints further dropped to approximately 16 per 100,000 DT acres – a nearly 63% decrease from 2016.

The ongoing trend of reduced incident reports helps confirm that the kinds of label restrictions and training requirements adopted by EPA starting in 2016 are effective, and therefore that EPA can reasonably anticipate that the more stringent restrictions now being considered will also be effective in practice. Moreover, applicator training and product familiarity continue to enhance label compliance and decrease the risk of off-site movement over time.

The data confirm that reports based on visible plant injury do not establish actual crop damage.

Puckered or cupped leaves on non-DT soybean plants are among the most common symptoms reported by those claiming off-target impacts. BASF studies submitted to EPA confirm that soybean yield potential and plant height are not substantially impacted even by significant amounts of visual plant injury (~22% to 36%). Data from Purdue University trials also confirmed that terminal growth inhibition combined with puckered leaves is a less common symptom than visual symptoms only and is usually a result of higher rates of exposure not associated with drift. In particular, when plants were exposed to dicamba at earlier stages of growth, complete recovery is likely. These data further confirm that reports alleging visual plant injury do not provide reliable evidence of actual harm. Moreover, the application date cut-off now proposed for BASF's new Engenia registration will further reduce the risk of the kinds of late-stage exposures that could result in yield loss.

[1] *See, e.g.*, http://herbicidesymptoms.ipm.ucanr.edu/MOA/Synthetic_Auxins/

BASF's new Engenia product has substantially improved use requirements that will dramatically reduce the risk of off-site movement.

Most importantly, BASF's proposed new Engenia registration will be substantially different from the product EPA registered in 2018. The new product carries substantial improvements that dramatically reduce the risk of harm from off-site movement. Because the new product differs substantially from the prior Engenia product used previously, the previous complaint history is of limited or no relevance to the potential risk of off-target harm, if any, associated with the new proposed Engenia product.

First, the new Engenia product mandates the use of a tank mix buffer adjuvant that will counter acidifying and/or competitive cation effects of certain tank mix products such as those containing glyphosate. Approximately 75% of Engenia applications have included a tank mix with glyphosate to provide effective broad-spectrum control of emerged weeds present in farmers' fields (glyphosate controls grass weeds not controlled by Engenia and provides overlapping control of other broadleaf weeds for more effective control). Glyphosate can lower the pH or acidify the spray solution increasing the potential for secondary or volatile loss of dicamba. BASF is making available a tank mix buffer adjuvant, Sentris™, that will provide growers with an effective means to comply with the new label requirement and manage the spray solution pH. Other buffer adjuvants that satisfy EPA parameters may also be used, and are expected to be available to growers as well. An approved adjuvant will be required for use with every tank-mixed Engenia application, regardless of whether a particular tank mix combination may be of concern, to ensure compliance and minimize the risk of volatilization. BASF's Sentris™ buffer has been tested in numerous studies across a range of laboratory and field conditions and has been found to consistently negate the pH and/or cation effects of approved tank mix products such as glyphosate. In addition, the Sentris™ buffer improves the ability to more easily clean dicamba from spray equipment reducing the chance of equipment contamination and later inadvertent application to a sensitive crop. The requirement to use an effective tank mix buffer with every Engenia application will eliminate the negative impact of glyphosate tank mixing. This measure alone dramatically reduces the potential for off-target movement due to volatility.

Second, the new Engenia product more than doubles the required downwind buffer distance from 110 to 240 feet. Extensive field and other data confirm that these buffers, standing alone, will be effective and will profoundly reduce the risk that off-site dicamba drift, if it occurs, would come into contact with non-target plants.

Third, the new Engenia product carries application cut-off dates of June 30 for soybeans and July 31 for use in cotton. Prohibiting late applications will reduce, even further, the risk that neighboring fields of non-DT soybean or other crops could experience any dicamba exposure from the use of Engenia at a time that might result in any actual crop harm (*e.g.*, yield impact). These cut-off dates will also reduce the likelihood of a temperature inversion at the time of application.

To the extent EPA seeks to estimate the magnitude of the risk of harm from off-site movement, that analysis must take into account the dramatic changes and improvements to Engenia. The scientific record provides comprehensive support for the conclusion that the combined effects of these improvements and use restrictions, among others, will dramatically reduce any risk of off-site movement or harm to non-target plants such that approving BASF's new Engenia registration will not pose any unreasonable risks to the environment from off-site impacts (regardless of whether past incidents claimed to have resulted from use of the prior products were over-reported or under-reported).

Compliance with label restrictions

The Ninth Circuit concluded that "[e]xtensive evidence in the record indicates that there is a risk of substantial non-compliance with the EPA-mandated label for the 2019 and 2020 growing seasons." *NFFC* at 1139. The Court concluded that EPA failed to acknowledge this consideration and the resulting risk of off-site harm from product misuse. *Id.*

In general, in making a FIFRA registration decision, EPA must consider potential risks of the product "when used in accordance with widespread and commonly recognized practice" and taking into consideration other "restrictions imposed" on the product and its use. FIFRA § 3(c)(5). Absent evidence that illegal use contrary to a particular product label has become a "widespread and commonly recognized practice" for a given product (which is highly doubtful given the significant civil and criminal penalties associated with such misuse), EPA is required to evaluate risk from the legal use of the product.

Even before adoption of the shorter, simplified label now being proposed (discussed below), growers have confirmed to EPA that the ongoing training and education of applicators has been successful. Applicators are committed to continuing this progress, and to ensuring successful use of OTT dicamba products on soybean and cotton crops, and to avoiding off-site movement by following label requirements. For example:

- "The auxin training program has proven very effective in North Carolina at reducing the incidents of drift resulting from Dicamba and other auxin herbicides. Our applicators also understand that effective weed control involves using a variety of modes of action to address and avoid resistance, including the OTT use of Dicamba products." (Letter from North Carolina Department of Agriculture & Consumer Services *et. al.* dated August 24, 2020).

- "While we acknowledge over the top dicamba has had a complicated history the last several years, we believe many of these challenges have been significantly reduced with label improvements and greater applicator training." (Letter from Iowa Soybean Association *et. al.* dated August 27, 2020).

- "U.S. cotton farmers have … reported their efforts to ensure that everyone involved in herbicide application on their farm have completed auxin training. The producers have provided to EPA their experiences with resistant pigweed prior to dicamba tolerant crops and emphasized their determination to preserve the use of the auxin herbicide systems." (Letter from National Cotton Council dated September 10, 2020).

- "We also support a conditional registration duration longer than the historical two years, coupled with a practical, detailed label and assertive training for applicators that capitalizes on previous growing season experiences to minimize any risks of product use." (Letter from American Soybean Association dated August 10, 2020).

Moreover, the new Engenia label for DT soybean and cotton uses has been substantially simplified and streamlined, and will further increase label compliance. The Ninth Circuit faulted the prior Xtendimax label as being "forty pages long, with myriad instructions and restrictions." *NFFC* at 1140.[2] The new Engenia label has been reduced significantly, to approximately 20 pages, removing extraneous information and separating other uses. The new label also includes a simplified up-front summary of the key use limitations for ease of reference and comprehension. Other label simplifications include replacing growth-stage application limits with simple calendar date cut-offs. Product use will continue to be limited to personal application by a state-licensed certified applicator. Each applicator must satisfy extensive Engenia training requirements, enforced by EPA and state authorities. This training is ongoing and continues to improve user understanding and compliance going forward, as reflected in the reduced number of complaints discussed above.

Alleged risk of "anti-competitive" effects on grower seed purchase decisions

The Ninth Circuit cited anecdotal claims that some growers felt "pressured" into planting DT soybeans to avoid a risk of harm from dicamba drift from the use of OTT dicamba products on neighboring soybean and cotton farms. Based on this, the Court stated that registering the products "creates a substantial risk that DT soybeans, and possibly DT cotton, will achieve a monopoly or near-monopoly." *NFFC* at 1143.

Specifically, with respect to the notion of a risk of a "monopoly or near-monopoly" in soybean and cotton seed sales, it should be noted that other agencies within the federal government, such as the Federal Trade Commission and the Antitrust Division of the Justice Department, are charged with implementing and enforcing the nation's

[2] As EPA is aware, it is not unusual for a pesticide product label to be complicated, or to span 40 pages or more. FIFRA is premised on the fact that growers are able to understand and comply with the mandatory label directions, and growers routinely do so. Nevertheless, the new Engenia label has been significantly shortened and simplified to further facilitate successful use.

antitrust laws. EPA lacks the authority or expertise to attempt to identify or regulate potential monopolies, and no such role is contemplated for EPA under FIFRA.

Moreover, the extensive economic benefits associated with DT soybean and cotton seeds explain grower adoption, including the flexibility to apply OTT dicamba products such as Engenia to effectively control glyphosate-resistant weeds, and the high-quality genetics perceived to be associated with the currently-available DT seed offerings.

Furthermore, the increase in dicamba-tolerant seed use from 2016 to 2018 is similar to the rate at which soybean farmers adopted glyphosate-tolerant varieties in the years immediately following their commercial introduction. Therefore, initial adoption rates have some relationship simply to the availability of a valuable new product. Also, from 2019 to 2020, the share of DT soybean and cotton seeds planted remained mostly flat, suggesting that the "pressure" concern identified by the Court did not materialize in the most recent growing season, and that growers who might wish to adopt DT seeds have (apparently) already done so. While not all acres planted with DT seeds are ultimately treated with dicamba, some growers of DT seeds plant them to preserve the option to use dicamba if adequate weed control cannot first be achieved with glyphosate.

In addition to the lack of evidence that any perceived "pressure" to adopt DT seeds was significant or widespread in the past, any such perception will be addressed by the changes to the Engenia product discussed above. These changes will dramatically reduce or eliminate the risk of off-site movement or harm to neighboring crops, and thus address the concerns identified by the Ninth Circuit.

Claimed risk of harming the "social fabric" of farming communities

The Ninth Circuit cited anecdotal reports of disputes among growers over alleged off-site dicamba crop damage, and concluded that: "[t]he severe strain on social relations in farming communities where the new dicamba herbicides are being applied is a clear social cost, but the EPA did not identify and take into account this cost." *NFFC* at 1143.

It is certainly true that many pesticide products and uses are controversial, and that OTT uses of dicamba have faced controversy. To the extent there is evidence of such issues, EPA should acknowledge and consider such evidence. Ultimately, however, the fact that social controversy exists cannot be taken by EPA as evidence that the alleged harm underlying that controversy has actually taken place or is likely to occur, or that the alleged harm constitutes an unreasonable risk, taking into account the substantial economic benefits to growers of a product like Engenia. FIFRA requires EPA to ground its determinations in science, not mere anecdotal claims.

In this case, as discussed above, the new Engenia product includes changes that will dramatically reduce or eliminate off-site harm. Accordingly, it is reasonable for EPA to conclude that any alleged social disputes arising from such alleged harm will be similarly reduced or eliminated. Moreover, given that the data now confirm that any perceived off-site crop impacts are not likely to result in economic harm, and not to

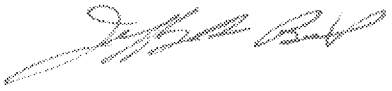
impact yield (and that use of OTT dicamba itself improves yield), EPA's proper role under FIFRA is to reach the appropriate scientific conclusions and to communicate those conclusions to society, including growers, by issuing an appropriate registration decision based on the evidence.

Importantly, any alleged social disruption cannot be resolved by EPA simply denying the registration. The fact is that many growers strongly support the registration of these products as a valuable and critical tool for effective control of glyphosate-tolerant weeds (the control of which is a substantial social benefit because such weeds otherwise negatively impact yield), while other growers have strongly objected to these products. Whether EPA approves or disapproves the registration, given the nature of the controversy some growers will feel aggrieved and feel that their interests have been harmed by unfounded claims advanced by other growers. In fact, the "social fabric" of farming communities was significantly harmed by the Court's ruling that vacated the dicamba registrations in the midst of the growing season. Similar harm would occur again if EPA were to deny the registration of more restricted dicamba products based on mere claims by growers who oppose dicamba.[3]

EPA's only legitimate role in addressing such a controversy is to render a neutral registration decision based on the scientific evidence. Doing so provides the best chance for any social friction among growers to be resolved based on the facts and evidence. To the extent a grower continues to allege some economic harm from pesticide misuse (or any other farming practice by a neighbor), the availability of tort remedies remains the appropriate resolution of such disputes. EPA has neither the expertise nor the authority under FIFRA to evaluate whether such claims have merit, or whether the nation's tort system is performing adequately to remedy any alleged economic harm.

Please contact me at (919) 225-9220 or jeffrey.birk@basf.com if you have any questions.

Respectfully Submitted,



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[3] News reports highlight the "no win" nature of the controversy that has been generated by activist claims and other factors. https://www.npr.org/2020/09/22/915354187/in-arkansas-backlash-against-pesticide-regulation-gets-personal.